CETAPHIL ACNE RELIEF BODY WASH- salicylic acid gel Galderma Laboratories, L.P.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active Ingredient

Salicylic Acid 2%

Purpose

Acne Treatment

Use

For the management of acne

Warnings

For external use only

When using this product

• skin irritation and dryness is more likely to occur if you use another topical acne medication at the same time. If irritation occurs, only use one topical acne medication at a time.

Stop use and ask a doctor if

irritation becomes severe.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Apply to dampened skin and gently massage. Rinse thoroughly with warm water. Pat dry. If bothersome dryness or peeling occurs, reduce application use.

Inactive Ingredients

BENZYL ALCOHOL, BUTYROSPERMUM PARKII (SHEA) BUTTER, COCAMIDOPROPYL BETAINE, GLYCERIN, GLYCINE SOJA (SOYBEAN) OIL, GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE, HYDROGENATED SOYBEAN OIL, HYDROXYPROPYL STARCH PHOSPHATE, LACTIC ACID, LAURIC ACID, PALMITIC ACID, PHENOXYETHANOL, SODIUM BENZOATE, SODIUM CHLORIDE, SODIUM HYDROXIDE, SODIUM LAUROYL GLYCINATE, SODIUM LAUROYL ISETHIONATE, STEARIC ACID, TETRASODIUM EDTA, WATER

Distributed by: Galderma Laboratories, L.P. Fort Worth, TX 76177 USA cetaphil.com

PRINCIPAL DISPLAY PANEL - 20 FL OZ bottle

#1 Doctor Recommended Sensitive Skincare Brand

Cetaphil®

ACNE RELIEF BODY WASH

Acne-Prone Skin

Maximum strength OTC formula to eliminate breakouts

24 hour dryness relief

Advanced Moisture Blend 2% Salicylic Acid Acne Treatment

5 skin sensitivity signs 20 FL OZ (591 mL) P55982-1





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Cetaphil® ACNE RELIEF Body Wash

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Inactive ingredients Benzyl Alcohol, Butyrospermum Parkii (Shea) Butter, Cocamido-Propyl Betaine, Glycerin, Glycine Soja (Soybean) Oil, Guar Hydroxypropyltrimonium Chloride, Hydrogenated Soybean oil, Hydroxypropyl Starch Phosphate, Lactic Acid, Lauric Acid, Palmitic Acid, Phenoxyethanol, Sodium Benzoate, Sodium Chloride, Sodium Hydroxide, Sodium Lauroyl Glycinate, Stearic Acid, Tetrasodium Lauroyl Isethionate, Stearic Acid, Tetrasodium Edta, Water

Questions or comments? 1-866-735-4137

GALDERMA

Distributed by: Galderma Laboratories, L.P. Fort Worth, TX 76177 USA

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cetaphil.com P55983-0



Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:0299-4121

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Salicylic Acid (UNII: O414PZ4LPZ) (Salicylic Acid - UNII:O414PZ4LPZ)	Salicylic Acid	20 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
Benzyl Alcohol (UNII: LKG8494WBH)	
Shea Butter (UNII: K49155WL9Y)	
Cocamidopropyl Betaine (UNII: 50CF3011KX)	
Glycerin (UNII: PDC6A3C0OX)	
Soybean Oil (UNII: 241ATL177A)	
Guar Hydroxypropyltrimonium Chloride (1.7 Substituents Per Saccharide) (UNII: B16G315W7A)	
Hydrogenated Soybean Oil (UNII: A2M91M918C)	
Lactic Acid, Unspecified Form (UNII: 33X04XA5AT)	
Lauric Acid (UNII: 1160N9NU9U)	
Palmitic Acid (UNII: 2V16EO95H1)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Sodium Benzoate (UNII: OJ245FE5EU)	
Sodium Chloride (UNII: 451W47IQ8X)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Sodium Lauroyl Glycinate (UNII: L54QIO80PN)	
Sodium Lauroyl Isethionate (UNII: M590021Z02)	
Stearic Acid (UNII: 4ELV7Z65AP)	
Edetate Sodium (UNII: MP1J8420LU)	
Water (UNII: 059QF0KO0R)	

ı	P	ackaging			
	# Item Code Package Description		Marketing Start Date	Marketing End Date	
	1	NDC:0299-4121- 00	591 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2022	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	01/01/2022	

Labeler - Galderma Laboratories, L.P. (047350186)

Establishment				
Name	Address	ID/FEI	Business Operations	
Fruit of The Earth, Inc		080086802	manufacture(0299-4121)	

Revised: 8/2022 Galderma Laboratories, L.P.